TAB 12B

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

_____X

THE CITY OF HUNTINGTON, : Civil Action

Plaintiff, : No. 3:17-cv-01362

V.

AMERISOURCEBERGEN DRUG CORPORATION, et al.,

Defendants. :

CABELL COUNTY COMMISSION, : Civil Action

Plaintiff, : No. 3:17-cv-01665

v. :

AMERISOURCEBERGEN DRUG CORPORATION, et al.,

Defendants. : x

BENCH TRIAL - VOLUME 22

BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

JUNE 8, 2021

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1
       about here?
 2
                 MS. SINGER: Prior. I'm sorry, Your Honor. Prior
 3
       to the 2007 Order to Show Cause and Immediate Suspension
 4
       Order.
 5
                 MR. NICHOLAS: I will renew my objection based on
 6
       vagueness and time period.
 7
                 THE COURT: All right. Overruled. He can answer
 8
       if he can.
 9
                 THE WITNESS: The distributor initiative was based
10
       on the systems that they were operating. That's why they
11
       were called in, because we wanted to make sure that they
12
       understood what their obligations were, and to make the
13
       appropriate corrections to their -- their systems. So --
14
       so, yes, I was aware of this system at that point in time.
15
       I was aware of all three, you know, the systems that they
16
       had.
17
                 BY MS. SINGER:
18
           And by all three, what do you mean, Mr. Rannazzisi?
       Q.
19
           The three defendants.
20
            And did you have reason to believe -- did you believe
21
       at the time that this Order to Show Cause and Immediate
22
       Suspension Order was issued that AmerisourceBergen's conduct
23
       was -- that its compliance deficiencies were national and
24
       systemic?
25
                 MR. NICHOLAS: Your Honor, I will object. I've
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1
       listened carefully to the question and the answer. There is
2
       no basis -- there is no foundation laid here for this
 3
       witness to answer that question.
 4
                 MS. SINGER: I think, Your Honor, he has just
       testified that he was familiar with all of their systems.
 5
 6
                 MR. NICHOLAS: That is all he has said about
 7
       AmerisourceBergen's program, is that he was familiar with
 8
       the system and the fact that they had a system, period.
 9
       Full stop.
10
                 THE COURT: Well, I'm going to overrule the
11
       objection and let him answer.
12
                 THE WITNESS: When the system did not identify
13
       these -- these orders as suspicious, I took that to be,
14
       again, a systemic failure in their system and, therefore,
15
       their system was not operating within the confines of
16
       1301.74(b) to identify and report suspicious orders.
17
            So, let's turn --
       Q.
18
                 MS. WICHT: Your Honor, I object to the legal
19
       conclusion stated by the witness.
20
                 MR. NICHOLAS: Yes. I was --
21
                 MS. WICHT: Sorry, Mr. Nicholas.
22
                 MR. NICHOLAS: Forgive me. I should have been the
23
       first one to make that objection, but that is the objection
24
       I would make, as well.
25
                 THE COURT: And I will sustain that objection.
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1
                 MS. SINGER: So, Your Honor, I would ask that --
2
       that the witness's testimony up until the legal conclusion
       be committed -- be permitted, meaning -- and I'm happy to
 3
       ask him again and with Your Honor's instruction that he not
 5
       offer a legal conclusion.
                 THE COURT: Well, ask him again and --
 6
 7
                 MR. NICHOLAS: Well, I'm standing up just in case.
       I don't know what -- I don't know what she's going to ask.
 8
 9
                 THE COURT: Well --
10
                 MS. SINGER: But you assume you're not going to
11
       like it, so fair enough.
12
                 THE COURT: Ask him the question and see if you
13
       can get around the legal conclusion.
14
                 MS. SINGER: All right.
15
                 BY MS. SINGER:
16
           All right. Mr. Rannazzisi, prior to the time that this
17
       Order to Show Cause and Immediate Suspension Order was
18
       issued -- now I have to remember the question -- had you
19
       reached a conclusion --
20
                 MS. SINGER: I'm sorry. Can I ask the court
21
       reporter to read back the question that I originally asked?
22
       Mr. Rannazzisi may be doing fine, but I may need a break,
23
       Your Honor.
24
            (Court reporter read back requested portion)
25
                 BY MS. SINGER:
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- 1 regard to the other objections.
- 2 BY MS. SINGER:
- 3 Q. Now, as with, as with other Orders to Show Cause
- 4 and Immediate Suspension Orders, did you approve and
- 5 recommend this Order to Show Cause and Immediate
- 6 Suspension Order to the deputy administrator?
- 7 A. Again, I reviewed, like the others, the Immediate
- 8 Suspension -- the Order to Show Cause and Immediate
- 9 Suspension Order. I gave my initial approval and sent it
- 10 up. Only the deputy administrator can make a decision on
- 11 imminent threat.
- 12 Q. And can you read Paragraph 5 of this Order to Show
- Cause and Immediate Suspension Order?
- 14 A. "Notwithstanding the large quantities of controlled
- substances ordered by Cardinal's top retail pharmacy
- 16 customers, Cardinal failed to conduct meaningful due
- diligence to ensure that the controlled substances were not
- 18 diverted into other than legitimate channels, including
- 19 | Cardinal's failure to conduct due diligence of its retail
- 20 pharmacy chain customers. Furthermore, Cardinal failed to
- detect and report suspicious orders of oxycodone products by
- 22 its pharmacy customers, as required by 21 C.F.R. 1301.74(b).
- 23 In addition, Cardinal's conduct described herein violated
- 24 the provisions of the administrative memorandum of
- 25 agreement."

```
1
            And does that accurately reflect DEA's assessment of
2
       Cardinal's distribution -- I'm sorry -- DEA's findings in
 3
       this investigation?
 4
       Α.
            Yes.
 5
            And do you believe that the failures described here
 6
       were limited to these customers of the Cardinal -- of that
 7
       Cardinal distribution center?
 8
                 MS. WICHT: Objection, foundation.
 9
                 THE COURT: Overruled.
10
                 THE WITNESS: Could you repeat the question one
11
       more time? I didn't catch it.
12
       BY MS. SINGER:
13
           Did, did, did the paragraph you just read
14
       accurately reflect DEA's -- I'm sorry. That's two
15
       questions ago.
16
            Were the failures described here in Paragraph 5 that
17
       you just read limited to the four Cardinal customers at this
18
       distribution center, or did you believe that they were
19
       systemic failings as well?
20
                 MS. WICHT: I'll object only to clarify that we're
21
       speaking within the scope of his own personal individual
22
       knowledge.
23
                 THE COURT: Well, overruled, if he knows.
24
                 THE WITNESS: Well, I believe that because there
25
       was, again, another systemic failure that was happening
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- 1 elsewhere as well.
- 2 BY MS. SINGER:
- 3 Q. Now, had DEA communicated with Cardinal prior to
- 4 issuing this Immediate Suspension Order about the issues
- 5 | raised in the Order to Show Cause?
- 6 A. Yes, I believe there were communications.
- 7 Q. And do you recall the details of those communications,
- 8 | how many, with whom, et cetera?
- 9 A. I believe the communications occurred at the division
- 10 level with DPM and the group supervisor as well as
- 11 headquarters staff.
- 12 Q. And do you recall whether -- roughly how many
- 13 | communications there were?
- 14 A. I don't recall.
- 15 **Q.** Is there a document that might refresh your
- 16 | recollection?
- 17 A. I'm sure there's a document that, that has the content
- of the discussions that, between -- yes, there should be a
- 19 document.
- 20 Q. And do you recall, did Cardinal challenge this
- 21 immediate -- this Order to Show Cause and Immediate
- 22 Suspension Order in Federal Court in the District of
- 23 Columbia?
- 24 A. Oh, yes, yes, they did.
- 25 Q. And do you recall whether you submitted a declaration

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1
                 THE COURT: Overruled.
2
                 THE WITNESS: No, they don't. It's just
 3
       transactions. It looks like transactions above a threshold.
 4
      That's basically it.
 5
      BY MS. SINGER:
 6
      Q. So did it give you information on why a distributor
 7
       thought DEA should be aware of any of those
 8
       transactions?
 9
           No, there's nothing, there's nothing in here that has
10
       any explanation of why it would be deemed suspicious.
11
      Q. And were these reports useful to DEA?
12
                 MR. SCHMIDT: Objection, foundation. I think he
13
       can answer as to himself, not as to DEA.
14
                 THE COURT: Well, if he knows. I'll overrule the
15
       objection.
16
            You can answer if you can, Mr. Rannazzisi.
17
                 THE WITNESS: To me, no, these, these have
18
      no value because all it is is reporting transactions over a
19
      threshold. I don't know anything about any of these
20
      pharmacies. I don't have an explanation of why this would
21
      be deemed suspicious. They're not, they're not given to us
22
      when discovered. It's just a monthly printout of
23
      transactions, you know, above a certain threshold. So, no,
24
       I -- no.
25
      BY MS. SINGER:
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1
            And when DEA received suspicious order reports as
 2
       opposed to excessive purchase reports, did DEA
       investigate those reports?
 3
 4
            Again --
 5
                 MR. NICHOLAS: Objection. I think this goes back
 6
       to the debate we had yesterday. And I'm not sure exactly
 7
       where we landed, but I think since the witness is unable to
 8
       provide any, any specific information here, I would object
 9
       based on, on foundation and lack of ability to probe as to
10
       whatever his answer might be.
11
                 MR. SCHMIDT: Join.
12
                 THE COURT: Well, the question was: When DEA
13
       received suspicious order reports as opposed to excessive
14
       purchase reports, did DEA investigate those reports?
15
            I think that's a perfectly proper question and I'll
16
       overrule the objection and you can answer it if you can, Mr.
17
       Rannazzisi.
18
                 THE WITNESS: I know investigative -- I know
19
       suspicious order reports were investigated. I know that.
20
       can't tell you every suspicious order report was ever -- you
21
       know, every one that was ever submitted was investigated.
22
       But I know they were investigated and I know that was the
23
       protocol to investigate those suspicious order reports.
24
       BY MS. SINGER:
25
            And did suspicious order reports sometimes lead to
       Q.
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1
       an action being taken against a registrant?
2
            Suspicious order reports, like I said before, are a
 3
       pointer system. So it would lead the investigators to, if
 4
       not open an investigation, assist in an on-going
 5
       investigation.
 6
       Q. Now, did DEA give these defendants feedback that the
 7
       excessive purchase reports that we just looked at weren't
 8
       helpful to DEA?
 9
                 MR. SCHMIDT: Objection as to time frame, if we
10
       could just specify the time frame.
       BY MS. SINGER:
11
12
       Q. This is all prior to the --
13
                 THE COURT: Overruled.
14
       BY MS. SINGER:
15
            Okay. Go ahead and answer, please.
16
                 THE COURT: Well, the time -- have you put a time
17
       frame on it?
18
                 MS. SINGER: I haven't, Your Honor.
19
       BY MS. SINGER:
20
            At any point during your tenure at DEA, did DEA
21
       tell defendants that these excessive purchase reports
22
       weren't helpful?
23
            Yes, during, during my tenure, we did, yes, absolutely.
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the record, he's testifying from his own personal

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MR. WESTFALL: Your Honor, just so it's clear on

24

- effective controls and I didn't get the first part.
- 2 Q. Yeah. In conducting inspections of defendants'
- 3 distribution centers during your tenure did DEA find the
- 4 defendants failed to maintain effective controls against
- 5 diversion?

- 6 A. Yeah. I don't recall. There were so many inspections
- 7 in the distributor -- the distributor population as a whole,
- 8 yes, I'm sure they have, but I just can't recall if these
- 9 three defendants had that type of, you know --
- 10 Q. And did your findings and visits -- and I'm sorry.
- Beyond inspections did DEA visit distribution centers
- 12 outside of the cyclic investigations?
- 13 A. DEA can go in on a -- on a -- you know, could go in a
- 14 | facility pretty much whenever they wanted. It's a question
- of whether we've actually done an inspection within a year
- 16 and whether we executed a notice of inspection but, yes, DEA
- 17 | could go into the facilities if need be.
- 18 Q. And did your findings during those inspections and
- 19 other visits inform the enforcement actions that DEA took
- 20 during your tenure as Deputy Assistant Administrator?
- 21 A. In some circumstances, yes.
- 22 Q. Now, in addition to inspections, did defendants meet
- with DEA to discuss their compliance programs in other
- 24 settings?
- 25 A. I -- I don't -- I don't recall that.

- Q. And do you know whether DEA provided feedback to these defendants on the design of their Suspicious Order

 Monitoring Systems?

 A. They may have said the system -- generally what they would say is the system looks -- looks like it's operational or it looks -- it looks like it's operating appropriately.

 That's about it. It can't -- it can't confirm it, but based
- That's about it. It can't -- it can't confirm it, but based on the policies and procedures that they're looking at, they would say it looks like it's operating appropriately.
 - Q. And did DEA have a policy or procedure of its own on whether it could approve a defendant or distributor's Suspicious Order Monitoring System?
 - A. No. There's no approval process. That's why they would say it's operating satisfactorily. From what you've shown me, it looks to be operating satisfactory, something to that, but there was never an approval given for a Suspicious Order Monitoring Program.
 - Q. And did DEA communicate to defendants that it could not approve their Suspicious Order Monitoring Systems?
 - A. Yes.

- Q. And do you know when those communications took place?
 - A. Just the letters to start off. The distributor initiative, then the letters following the distributor initiative. Then the Memorandums of Understanding and the settlement agreements. They just continued on and on.

- 1 Are you aware that during your tenure defendants used 2 thresholds as one -- as a way of identifying suspicious 3 orders? 4 I'm aware that the defendants used hard -- some of the defendants used hard numbers during that time period, yes. 5 6 And what do you mean by "hard numbers"? 7 Yeah. So, there would be a ceiling level or they would create -- yeah. There would be a ceiling level where that 8 9 -- that would be the ceiling and then, anything above that 10 would be however they termed it, a breach, order of 11 interest. 12 And do you know what defendants' thresholds were based 13 on during your tenure as Deputy Assistant Administrator? I'm not sure. 14 Α. 15 Do you know whether defendants used any kind of 16 multipliers of past orders as a vehicle for setting 17 thresholds? 18 MR. SCHMIDT: Objection, leading after the witness 19 has said he doesn't know. 20 THE COURT: Sustained. 21 BY MS. SINGER: 22 To your knowledge, did DEA ever provide guidance to 23 defendants about whether they could use thresholds or
 - defendants about whether they could use thresholds or multipliers of orders to identify suspicious orders?

 A. No. As far as I know from my time there, no. That

25

A. No. 715 fat as I know from my time there, no. That

```
1
       would have never -- that would not have occurred during my
2
       time, yes.
 3
            And did -- all right. Moving on to another topic --
       Q.
 4
                 THE COURT: This may be a good time for a break.
 5
                 MS. SINGER: Yes, Your Honor.
 6
                 THE COURT: We'll come back about 3:30. It looks
 7
       like we're at a convenient stopping point.
 8
            (Recess taken)
 9
            (Proceedings resumed at 3:31 p.m. as follows:)
10
                 THE COURT: All right, Ms. Singer.
11
       BY MS. SINGER:
12
            All right, Mr. Rannazzisi, just a few more topics
13
       this afternoon.
14
            Now, I think you mentioned at the start of your
15
       testimony that healthcare providers who prescribe controlled
16
       substances are registered with the DEA; is that correct?
17
       Α.
            Yes.
18
            And based on your experience at DEA, were most
19
       healthcare providers prescribing appropriately?
20
            Yes.
       Α.
21
            And have you offered any numbers as to what percentage
22
       of the universe of prescribers you think are prescribing
23
       appropriately and consistent with the law?
24
            Yeah. We usually said 99 percent of the prescribers in
25
       the United States are operating -- treating their patients
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1
       appropriately.
2
            And have you ever done the math to figure out how many
 3
       prescribers then aren't prescribing lawfully?
 4
            Do the math as far as -- I'm sorry.
 5
            So how many -- that one percent, how many prescribers
       is that?
 6
 7
            Oh, depending on the population of prescribers at the
 8
       time. It's thousands, you know, over 10,000, 15,000.
 9
            And in your experience, how much harm can 16,000
10
       prescribers who are prescribing unlawfully do?
11
                 MS. WICHT: Objection, vague and lack of
12
       foundation.
13
                 MR. NICHOLAS: And speculative and leading.
14
       object as well.
15
                 THE COURT: Sustained.
16
       BY MS. SINGER:
17
       Q. Can DEA take action to investigate or revoke the
18
       registration of all of those prescribers?
19
            It would -- that is a lot of prescribers and that would
20
       be a lot of -- we -- no, we couldn't do that, not with the
21
       manpower that we had at the time and now -- well, I don't
22
       know what it is now, but when I was there, that would have
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been an awful lot of work and quite a bit of -- I just don't think we could have handled thousands of Orders to Show Cause and Immediate Suspension Orders.

23

24

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1
       I'm sorry. Let me rephrase. I'm sorry. I'll take one
2
       more crack at this.
 3
            Did you observe that DEA's enforcement activities
 4
       transitioned to heroin as a result of the diversion of
 5
       prescription opioids?
 6
                 MR. NICHOLAS: I would interpose the same
 7
       objection.
 8
                 MR. SCHMIDT: Same, scope and expert opinion.
 9
                 THE COURT: I'm going to sustain the objection,
10
       Ms. Singer.
11
                 MS. SINGER: We'll move on.
12
       BY MS. SINGER:
            Mr. Rannazzisi, for our last substantive topic I
13
14
       want to turn to quota and it's something I think we've
15
       talked about for a while.
16
            Can you briefly at a 20,000-foot level explain to the
17
       Court how quota for controlled substances works?
18
            The quota is an estimate of the total amount of a
19
       specific substance that can be made in the United States.
20
       It's governed by 21, U.S.C., 826 which provides a road map
21
       of what we need to include in our assessment in order to
22
       establish that quota.
23
            It's -- during my time, it was only established by a
24
       base code of drug. And what that means is we'll establish
25
       quota for hydrocodone. That's it. But not by dosage units,
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but by the amount of powder, the amount of drug that's actually being made.

Now, Congress gave us many different things to look at to establish this quota, knowing that the quota was necessary, not only because, one, it was required under, under UN treaties, but the second reason was Congress wanted to ensure that there was enough drug in the system to meet the legitimate medical, scientific, and industrial needs of the country. It's in 826.

What Congress, and what we're -- our charge was under 826 is to ensure that legitimate patients were getting their medication and not having shortages so a patient would do without. That was the whole basis of the quota.

The problem with quota is there's so many different things involved that you have to look at not just how much is being allowed to be made for patients, but also how much is being allotted for research and development, for validation studies, for export, for all those things that are necessary for scientific and industrial purposes. That quota will never -- would never get to a patient.

So there's two parts to quota. There's a first part where it's the amount of drug that would go to a patient, go to patient population. And the second part of quota is the amount of drug that goes to research development, export, validation, scientific and medical needs. That's how quota

- is generally set up. But it's -- we're required to follow
 the road map that Congress gave us in 826.
 - Q. All right. I was going to put up a slide, but I don't know that you need to see the statute, Mr. Rannazzisi.

Did you take -- I'm sorry. What was your role at DEA when you were Deputy Assistant Administrator with respect to setting quota?

A. I oversaw the quota unit, the UN reporting quota unit.

And that was a group of scientists. And those scientists

day in and day out would look at quota requests and look at

the available materials, what both the manufacturers

requested and what we could find, and then make a

determination if their quota request was in line with how

much need there would be.

Now, my job was to look at what they did and eventually sign off on their letters, but also sign off on the overall aggregate quota so the administrator could certify it and publish it.

- Q. And in your role in overseeing the quota section and making recommendations to the administrator --
- A. Deputy administrator.

- **Q.** -- deputy administrator, did you also take diversion 23 into account?
 - A. Yes. There's, there's a specific provision in the 826 that allows us to look at other things, and we did take

diversion into account.

- Q. Now, did quota for oxycodone and hydrocodone increase significantly during your tenure?
- **A.** Absolutely.
- Q. And why was that?
 - A. Because part of the quota involves the amount of disposal or the amount that's being, that's being either prescribed out or used in hospitals. And as that number kept going up, we would have to adjust the quota every year to ensure that there was enough quota for patients.

So the way it worked was if, if more prescriptions were going out of pharmacies, if more patients in hospitals were getting more drug, that quota was going to increase because we have to meet the needs of the patient population.

But in the same token, we also had during that time period research on certain drugs, research on new formulations of, say, hydrocodone or oxycodone. And the researchers, the companies that were conducting the research, that were conducting validation, they had to have quota.

Now, that quota may never, ever see a patient, but it had to be given out because if we can't give them the quota for, for that research and development, for the industrial use, for the export, if they can't get that, then they can't continue their research.

So we had to make sure that there was enough in place to take care of the patients, but then also to make sure there was enough to handle the research and development and all the other things that go on with scientific research regarding specific drug products.

- Q. So, Mr. Rannazzisi, as the opioid epidemic and opioid diversion grew, why didn't DEA lower quota?
- A. You can't just lower quota. It, it doesn't work that way. And I know people have said this over and over again.

 Quota -- it's a scientific and mathematical exercise to ensure that there's enough drug in the system.

I always think of it this way. If you have 100 people and all of those people are trying to get oxycodone and some of them are, are drug seekers who shouldn't have it and some of them are legitimate patients that need it, maybe they're palliative care, maybe they're chronic pain, but they need that drug, the quota is established so they will get their drug.

But if I come in and say, you know what, I'm just going to cut it by 20 percent, then that's 20 percent less but that patient -- the patient population and those drug seekers are competing for now 20 percent less. And that's how shortages occur.

I can't do anything about the people who are seeking drugs other than fine them and either get them help or put

them in jail. But I have to maintain enough drug in the system so those legitimate patients, palliative care, hospice, end of life care, those patients have their medication because if I don't do that, I'm not meeting my charge under 826. And I'm not doing the patients any good either.

And, and that's my problem. I'm, I'm -- we're balancing -- we're doing this balancing act to ensure that there's enough drug in the system, but not enough drug where it could sit on a shelf somewhere so somebody could break into a facility and steal it. And that's the problem.

And we didn't even talk about inventory because 826 requires us to give a percentage of inventory allotment in addition to the quota.

So there is so many different dynamics with quota. So when I hear people say just reduce it by 20 percent, well, we might reduce it by 20 percent, but if we don't reduce the amount of patients that are actually seeking -- that need that drug by 20 percent, then, then we're going to have a shortage.

And a perfect example of that, if I may, a perfect example of that is hydrocodone. Hydrocodone at one point in time was the number one drug in the United States. It wasn't the number one controlled substance. It was the number one drug in the United States. More people had

prescriptions of hydrocodone than any other drug.

We knew that was a problem between the internet and the pill mills and we decided to make a change. We went through the controlled substances. We decided we were going to take hydrocodone and down-schedule it from Schedule III to Schedule II.

Now, that's a very important -- that's a very important distinction. A Schedule II controlled substance, there is no refills. You have to give a written prescription. A Schedule III controlled substance, you have to go -- you could have five refills, you don't need a written prescription. You could call it in.

When we made that change in 2014, by 2017 hydrocodone had decreased dramatically. The number of prescriptions went down. It, it was reduced from the number one drug to way down the list.

Now, why was that? Because we required the doctors to change the way they did business with hydrocodone. They could no longer call it in, no refills. They had to write that prescription.

And that caused the quota to decrease dramatically. Within three years, it went down almost 33 percent or something like that.

That's how quota works. It's based on need. It's based on the patient need, not the, not the people who are